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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,368	01/12/2006	Atsushi Yamagishi	284112US0PCT	7782
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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER SUTTON, DARRYL C	
			ART UNIT 1612	PAPER NUMBER
			NOTIFICATION DATE 10/31/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/564,368	Applicant(s) YAMAGISHI ET AL.	
	Examiner DARRYL C. SUTTON	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/23/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the amendment filed 07/15/2008. New claims 12-21 have been added. Claim 1 has been canceled.

Applicant's arguments filed 07/15/2008 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Objections

Claims 20 and 21 are objected to because of the following informalities: As written, the claims are drawn to a "production", and should be drawn to a "product". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-7, 9 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,858,333) in view of Tomlinson et al. (U.S. 4,048,300).

Winston teaches an improved 2 part product for remineralizing or mineralizing teeth with a separating means for separating the components (Abstract), and a two part packaged product (page 42, lines 4-20). Winston also teaches an embodiment of the product which contains sodium fluoride and monoammonium phosphate in one component with an aqueous pH of 5.38 and calcium malonate in the other component with an aqueous pH of 6.83 (page 61, Example G, page 27, lines 23-28, page 59, lines 14-20, page 64, lines 10-14). Water soluble inorganic phosphate salts for use in the invention include alkali and ammonium salts of orthophosphoric acid (page 28, lines 15-22). Non-limiting examples of oral products include, tooth pastes, gels, mouthwashes, mouthrinses and the like. The oral product contains a discrete cationic part and a discrete anionic part, the two parts being separate from one another until the product is used (column 4, lines 55-59, column 6, lines 57-65). The anionic part contains at least one water soluble fluoride salt (column 8, lines 54-56). Water soluble fluoride salts, including alkali metal monofluorophosphates can be used in the invention (column 9, lines 1-19). Calcium glycerophosphate is a water-soluble calcium compound that has been used in two part compositions for remineralization of teeth.¹ Typically, at least about 10 seconds is required for diffusion of the remineralizing concentration of calcium and phosphate ions (column 10, lines 30-32).

¹ Usen et al., U.S. 5,605,675, Abstract, column 5, lines 10-20.

Art Unit: 1612

Winston et al. does not teach the method of alternately applying the separate compositions.

Tomlinson et al. teach dental preparations, such as toothpastes, tooth powders, gels and mouth washes, having calcium and phosphate components (Abstract, column 10, lines 28-30, column 18, lines 40-41). The novel compounds of the invention can be used in oral preparations and provide a long-term source of components for the remineralization of dental enamel (column 6, lines 52-58). Tomlinson teaches a composition with a first component comprised of fluoride and orthophosphoric acid with a pH of about 3 to 4; and a second component comprised of comprised of a calcium salt having a pH of about 7 (column 9, lines 28-39). Tomlinson teaches a method of alternately applying the compositions to the teeth. The teeth are subjected to fluctuating pH in the presence of fluoride, orthophosphate, and calcium ions which not only serves to prevent loss of calcium and orthophosphate ions from dental enamel, but also facilitates growth and development of the apatite crystals so that some remineralization of pits and fissures in the tooth enamel occurs. Optimum incorporation of fluoride ions into the apatite crystals structure occurs as the pH range rises from about 4 to about 7 (column 8, lines 47-68, column 17, Example 12). Apatite material containing fluoride containing materials serves to provide anti-caries protection and remineralization (column 10, lines 39-44). When orthophosphoric acid is used, an additional source of calcium ions is required such as from calcium carbonate (column 5, lines 24-27).

Art Unit: 1612

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Winston et al. to the method of alternately applying the separate compositions to teeth of Tomlinson et al. motivated by the desire to facilitate the remineralization and anti-caries protection of pits and fissures in tooth enamel by simultaneously producing the optimum incorporation of fluoride ions as taught by Tomlinson et al.

In regards to claim 4, it is prima facie obvious to select a compound based on its suitability for its intended purpose. See MPEP 2144.07. Therefore, it would have been obvious to modify the composition of Winston to contain calcium glycerophosphate as a calcium source.

In regards to claim 6, where the general conditions of a claim are disclosed in the prior art, it is not inventive to determine the optimum or workable ranges through routine experimentation. See MPEP 2144.05. Therefore, the remineralization of teeth is optimized by varying the ratio of the components through routine experimentation.

Claims 14-17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,858,333) and Tomlinson et al. (U.S. 4,048,300) as applied to claims 2, 3, 5-7, 9, 12-17 and 21 above, and further in view of Grabenstetter et al. (U.S. 4,083,955).

Winston et al. is discussed above.

Winston et al. does not teach the times required for application.

Tomlinson et al. is discussed above.

Tomlinson et al. does not teach the times ranges for application of each component is from 5 to 30 seconds.

Grabenstetter et al. teach two compositions comprised of a cation, i.e. calcium, and an anion, i.e. phosphate which are sequentially applied to dental enamel resulting in mineralization of dental enamel (Abstract). The sequential application consists of two steps which may be performed in any order (column 2, lines 13-20). While the length of contact is not critical, it is necessary for the length of time to be great enough to allow diffusion of the ions through the tooth's surface (column 2, lines 51-56). The components can be sequentially delivered to the surface of the tooth by means of two separate delivery vehicles, each containing one component. Examples of two vehicle systems are mouthwash-mouthwash, toothpaste-toothpaste, toothpaste-mouthwash; and so forth.

Grabstetter et al. do not teach the composition of claim 9.

In regards to claims 14-17, where the general conditions of a claim are disclosed in the prior art, it is not inventive to determine the optimum or workable ranges through routine experimentation. Therefore, the remineralization of teeth can be optimized through routine experimentation by varying amount of each component applied to the teeth and the amount of time each component is applied to the teeth; and by varying the amount of repetitions of the method.

In regards to claim 21, it would have been obvious to modify the delivery vehicle of each component since it is well known in the art that combinations of different delivery vehicles has been used to facilitate tooth remineralization.

Claims 8, 10, 11, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,858,333) and Tomlinson et al. (U.S. 4,048,300) as applied to claims 2-7, 9 and 12-15 above, and further in view of Wiesel (U.S. Patent 6,287,120).

Winston et al. is discussed above.

Winston et al. do not teach a carrier selected from paper, cloth, nonwoven fabric, absorbent cotton, sponge or porous film.

Tomlinson et al. is discussed above.

Tomlinson et al. do not teach a carrier selected from paper, cloth, nonwoven fabric, absorbent cotton, sponge or porous film.

Wiesel teaches an embodiment of a carrier coated with a paste, gel or solution which contains medicaments which promote the repair or remineralization of tooth enamel (Abstract, column 8, lines 28-36). Wiesel teaches that the carrier is a non-woven, porous material which is first dipped in one solution and that additional solution may be applied to the porous material while it remains on the patient's teeth (column 3, lines 65-67, column 4, lines 1-5).

Wiesel does not teach a composition comprised of two components.

At the time of the invention it would have been obvious to modify the product and method suggested by combining Winston et al. and Tomlinson et al. to include the carrier of Wiesel since the method of applying compositions for remineralization of teeth with a carrier was known in the art.

Art Unit: 1612

In regards to claim 11, it would have been obvious to impregnate the carrier with water immediately prior to application to a tooth motivated by the desire to mix either composition with water to produce either phosphate or calcium ions before applying the device to teeth.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,858,333), Tomlinson et al. (U.S. 4,048,300) and Wiesel (U.S. Patent 6,287,120) as applied to claims 8, 10, 11, 18 and 19 above, and further in view of Grabenstetter et al. (U.S. 4,083,955).

Winston et al. is discussed above.

Winston et al. does not teach a product for dental treatment comprised of a carrier.

Tomlinson et al. is discussed above.

Tomlinson et al. does not teach a product for dental treatment comprised of a carrier.

Wiesel is discussed above.

Wiesel does not teach a product comprised of a mouthwash and a dentifrice.

Grabenstetter et al. is discussed above.

Grabenstetter et al. does not teach a product comprised of a carrier.

At the time of the invention it would have been obvious to modify the product suggested by combining Winston et al., Tomlinson et al., Wiesel to be comprised of a

Art Unit: 1612

mouthwash and dentifrice since the components for remineralizing teeth can be applied in different delivery vehicles as taught by Grabenstetter et al.

Applicant alleges that unexpected and surprising results from the method of alternately administering the components of the composition and has provided a 1.132 declaration to substantiate the allegation. The declaration has been considered and the Examiner disagrees.

The Examiner points to the teaching of the prior art, Tomlinson, cited above. Tomlinson teaches a composition with a first component comprised of fluoride and orthophosphoric acid with a pH of about 3 to 4; and a second component comprised of comprised of a calcium salt having a pH of about 7 (column 9, lines 28-39); and, that optimum incorporation of fluoride ions into the apatite crystals structure occurs as the pH range rises from about 4 to about 7 (column 8, lines 47-68, column 17, Example 12). This pH fluctuation is created by alternately applying the calcium and phosphate components of the composition to the teeth. One of ordinary skill in the art would reasonably expect that fluoride incorporation would be optimal when compositions of substantially the same compounds are alternately applied to teeth; and therefore the findings of Applicant are not unexpected as declared by Applicant in the 1.132 declaration.

After analyzing, even assuming *arguendo* that unexpected results have been shown, the claims would not be commensurate with the scope of those showings.

Art Unit: 1612

In Example 1 and 2, component A, Applicant has used only sodium fluoride, not all fluoride ion-supplying compounds; phosphoric acid, not all inorganic phosphoric acids; and water. The component is at a pH of 3.6, not all pH within the range of 2 and 6; component B, Applicant has only used calcium glycerophosphate, not any calcium salt of an organic acid ; sodium monofluorophosphate, not all monofluorophosphates; and the pH is 8.1, not all pH within the range of 6-12. In Example 1, component B is not wetted. The form of the components is not provided in either Example 1 or 2 whereas the claims specify A and/or B being a powder, liquid liniment, a gel, a paste, a dentrifice, a solution or the combination of a mouthwash, A, and a dentrifice, B. Neither component is supported on a carrier selected from the group consisting of paper, cloth, non-woven fabric, absorbent cotton, sponge and porous film.

In Example 3, component A, Applicant has used only sodium fluoride, not all fluoride ion-supplying compounds; phosphoric acid, not all inorganic phosphoric acids; and water. The component is at a pH of 4.5, not all pH within the range of 2 and 6; component B, Applicant has only used calcium glycerophosphate, not any calcium of an organic acid; sodium monofluorophosphate, not all monofluorophosphates; and the pH is not provided, not all pH within the range of 6-12. The dental treating agents are specified as application and mouthrinsing; not either A and/or B being a powder, liquid liniment, a gel, a paste, a dentrifice, a solution or the combination of a mouthwash, A, and a dentrifice, B. Neither component is supported on a carrier selected from the group consisting of paper, cloth, non-woven fabric, absorbent cotton, sponge and porous film.

In Example 4, component A, Applicant has used only sodium fluoride, not all fluoride ion-supplying compounds; phosphoric acid, not all inorganic phosphoric acids; and water. The component is at a pH of 5, not all pH within the range of 2 and 6; component B, Applicant has only used calcium glycerophosphate, not any calcium of an organic acid; sodium monofluorophosphate, not all monofluorophosphates; and the pH is not provided, not all pH within the range of 6-12. The dental treating agents are in specified as a dentrifice, A, and a mouth wash, B; not either A and/or B being a powder, liquid liniment, a gel, a paste, a dentrifice, a solution or the combination of a mouthwash, A, and a dentrifice, B. Neither component is supported on a carrier selected from the group consisting of paper, cloth, non-woven fabric, absorbent cotton, sponge and porous film.

In Example 5, Applicant has used only sodium fluoride, not all fluoride ion-supplying compounds; phosphoric acid, not all inorganic phosphoric acids; and water. The component is at a pH of 4.5, not all pH within the range of 2 and 6; component B, Applicant has only used calcium glycerophosphate, not any calcium of an organic acid; sodium monofluorophosphate, not all monofluorophosphates; and the pH of 9, not all pH within the range of 6-12. The dental treating agents are in specified as two mouth washes, A and B; not either A and/or B being a powder, liquid liniment, a gel, a paste, a dentrifice, a solution or the combination of a mouthwash, A, and a dentrifice, B. Neither

Art Unit: 1612

component is supported on a carrier selected from the group consisting of paper, cloth, non-woven fabric, absorbent cotton, sponge and porous film.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1612

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612